NEW, CONTINUATION, DIVISIONAL OR CONTINUATION-IN-PART APPLICATION UNDER 37 C.F.R. §1.53(b)

Attorney Docket No. 8674-000004

Express Mail Label No. EL486599956US

Date May 26, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Hon. Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

Transmitted herewith for filing under 37 C.F.R §1.53(b) is a patent application for SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITOIN FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE.

identified by: [ ] First named inventor _____
or [X] Attorney Docket No. (see above)

1. **Type of Application**

[X] This application is a new (non-continuing) application.

[ ] This application is a [ ] continuation / [ ] divisional / [ ] continuation-in-part of prior application No. ____. Amend the specification by inserting before the first line the sentence:

--This is a [continuation/division/continuation-in-part] of United States patent application No. ____, filed ____.--

[ ] The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

If for some reason applicant has not requested a sufficient extension of time in the parent application, and/or has not paid a sufficient fee for any necessary response in the parent application and/or for the extension of time necessary to prevent the abandonment of the parent application prior to the filing of this application, please consider this as a Request for an Extension for the required time period and/or authorization to charge our Deposit Account No. 08-0750 for any fee that may be due. THIS FORM IS BEING FILED IN TRIPLICATE: one copy for this application; one copy for use in connection with the Deposit Account (if applicable); and one copy for the above-mentioned parent application (if any extension of time is necessary).

2. **Contents of Application**

a. [X] Specification of 15 pages;
[ ] A microfiche computer program (Appendix);
[ ] A nucleotide and/or amino acid sequence submission;

[ ] Because the enclosed application is in a non-English language, a verified English translation [ ] is enclosed [ ] will be filed.

[ ] Cancel original claims ____ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing date purposes.)

b. [ ] Drawings on ____ sheets;

c. [X] An unsigned Oath/Declaration is enclosed. A signed Oath/Declaration will be filed in accordance with 37 C.F.R. §1.53(f).

The enclosed Oath/Declaration is [ ] newly executed / [ ] a copy from a prior application under 37 C.F.R. §1.63(d) / [ ] accompanied by a statement requesting the deletion of person(s) not inventors in the continuing application.

d. **Fees**

FILING FEE CALCULATION	Number Filed			Number Extra		Rate		Basic Fee $690.00
Total Claims	18	–	20 =	0	×	$18.00	=	0.00
Independent Claims	4	–	3 =	1	×	$78.00	=	78.00
Multiple Dependent Claim(s) Used						$260.00	=	
FILING FEE – NON-SMALL ENTITY								768.00
FILING FEE - SMALL ENTITY: Reduction by 1/2 [ ] Verified Statement under 37 C.F.R. §1.27 is enclosed. [ ] Verified Statement filed in prior application.								
Assignment Recordal Fee ($40.00)								
37 C.F.R. §1.17(k) Fee (non-English application)								
TOTAL								**768.00**

[ ] A check is enclosed to cover the calculated fees. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 08-0750. A duplicate copy of this document is enclosed.

[X] The calculated fees will be paid within the time allotted for completion of the filing requirements.

[ ] The calculated fees are to be charged to Deposit Account No. 08-0750. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to said Deposit Account. A duplicate copy of this document is enclosed.

3. **Priority Information**

[ ] **Foreign Priority**: Priority based on _____ Application No. _____, filed _____, is claimed.

[ ] A copy of the above referenced priority document [ ] is enclosed / [ ] will be filed in due course, pursuant to 35 U.S.C. §119(a)-(d).

[ ] **Provisional Application Priority**: Priority based on United States Provisional Application No. ____, filed ____, is claimed under 35 U.S.C. §119(e).

Attorney Docket No. 8674-000004

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4. **Other Submissions**

[ ] A Preliminary Amendment is enclosed.

[ ] An Information Disclosure Statement, ____ sheets of PTO Form 1449, and ____ patent(s)/publications/documents are enclosed.

[ ] A power of attorney

[ ] is submitted [ ] with the new Oath/Declaration.

[ ] is of record in the prior application and [ ] is in the original papers / [ ] a copy is enclosed.

[ ] An Assignment of the invention

[ ] is enclosed with a cover sheet pursuant to 37 C.F.R. §§3.11, 3.28 and 3.31.

[ ] is of record in a prior application. The assignment is to ____, and is recorded at Reel ____, Frame(s) ____.

[ ] An Establishment of Assignee's Right To Prosecute Application Under 37 C.F.R. §3.73(b), and Power Of Attorney is enclosed.

[X] An Express Mailing Certificate is enclosed.

[ ] Other: _____

_____

Attention is directed to the fact that the correspondence address for this application is:

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Respectfully,

Date May 26, 2000
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05-30-00

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May 26, 2000

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

EXPRESS MAILING CERTIFICATE

Applicant: Pawan Seth

Serial No (if any):

For: SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITION FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE

Docket: 8674-000004

Attorney: Monte L. Falcoff

"Express Mail" Mailing Label Number EL486599956US

Date of Deposit . . . . . May 26, 2000

I hereby certify and verify that the accompanying New Application Transmittal Letter (in triplicate); 15-Page Patent Application; Unsigned Declaration and Power of Attorney (is) are being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service under 37 C.F.R. 1.10 on the date indicated above and (is) are addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Christine M Kaffko
Signature of Person Mailing Document(s)

SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITION FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE

BACKGROUND OF THE INVENTION

Food effect is a well-known phenomenon that can adversely affect the pharmacokinetics of drug distribution in the body. As a result, many drugs have to be taken either in fasted or fed conditions to achieve the optimum effect. Well known examples include carbamazepine tablets (to be taken with meals), captopril tablets (to be taken one hour before meals), or azithromycin tablets (to be taken 2 hours after meal), while some other drugs remain unaffected by food, as amoxicillin for example.

For this reason, FDA recommends to test bioequivalency of drug products either under fasted or fed conditions, depending on the drug. Moreover, in the latter case the meal itself is standardized.

Little formulation work has been conducted to date in order to overcome this food effect disadvantage.

US-P-5529791 describes an extended release formulation of diltiazem pellets coated with either cellulosic or synthetic polymers, and absence of food effect is reported. However, no link is explained between the composition of the product and the absence of food effect.

Benziger et al., J.Pharm.Sci., 85,4, pp.407-410 (1996) compared the bioavailability of oxycodone formulated as an immediate release aqueous solution or as extended release tablets, under fasted or fed conditions and found a significant difference in availability of the solution while no difference could be observed with the extended release tablets. These authors related the absence of food

effect to the use of extended release tablets rather than to any specific formulation parameter.

US-P-5879714 a drug and a water insoluble polymer are mixed into a molten carrier, preferably water-soluble. The only example provided in this patent consists in melting PEG 8000 at 120°C and dispersing nifedipine, stearic acid and Eudragit RSPO in it. After cooling, the solidified mixture is ground into granules. Heat sensitivity of many drugs seems is a major concern when considering applying the process thereto. Absence of food effect is not disclosed but it is indicated that hydrophilic matrix systems are said to be more likely to induce food effect than the disclosed formulation.

US-P-5580578 provides controlled release formulation having a coating consisting essentially in methacrylic copolymers, said coating having been oven cured. Examples disclose compositions comprising a core comprising thee active ingredient (e.g. hydromorphone hydrochloride), an intermediate layer comprising hydroxypropylmethylcellulose and the cured overcoat based on Eudragit. After oven curing, drug products tested clinically were found to be exempt of food effect (this was however not justified by formulation parameters). The coating is comprised of sustained release acrylic copolymers of the type Eudragit RS (comprising optionally Eudragit RL).

None of the above documents teaches or suggests the present invention.

SUMMARY OF THE INVENTION

The invention relates to a novel sustained release pharmaceutical composition that is free or devoid of food effect and to a method for alleviating the food effect in the drug release.

The invention thus provides a sustained release composition free of food effect comprising:

(a) a core comprising an active ingredient; and

(b) a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide.

The instant invention also provides a process for alleviating food effect in a pharmaceutical composition, comprising the step of coating a core comprising an active ingredient with a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide.

DETAILED DESCRIPTION

The present invention consists in a coated tablet.

The core of said tablet comprises one or several pharmacologically active substances chosen among those of which absorption is known to be influenced by food intake. Examples of such drugs comprise carbamazepine, verapamil, nifedipine, felodipine, amlodipine, diltiazem, oxibutynin, doxazocin, venlafaxin, captopril, enalapril, fenofibrate, without being restricted to them.

The core usually comprises from 20 to 80% of active ingredient. It also generally comprises 10 to 80% by weight of a gelling agent, which can be chosen among hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethyleneglycol and polyethylene oxide. The core additionally comprises classical excipients, like (microcristalline) cellulose, lubricants, silicon dioxide, desintegrating agents, etc.

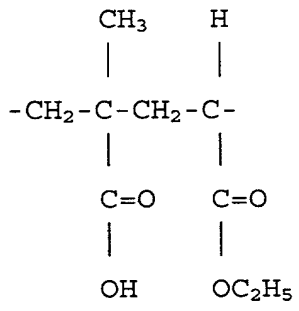
The core may be obtained by preparing a mixture of the starting compounds and direct compression. Alternatively, the gelling agent and the active ingredient are granulated together, and the resulting granules, optionally with other excipients, are compressed into a tablet.

Surprisingly, it has been discovered that the coating of the composition presents the unique feature of preventing the whole dosage form from being influenced by food intake.

This coating comprises a functional coating which comprises, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide.

The gastroresistant polymer withstands the acidic medium of the stomach and the duodenum, but will dissolve in the intestines, as soon as the pH reaches a predetermined level (e.g. above 5.5 or above 7). This gastroresistant polymer can be selected from the group consisting in (uncured) poly(meth)acrylic acid, cellulose and alkylcellulose-phtalates. Molecular weight can vary within broad limits as will recognize the skilled man. The term "uncured" is used to differentiate over US-P-5580578.

Preferably, it is of the type of Eudragit L30D55. One preferred polymer is an anionic copolymer on the basis of methacrylic acid and acrylic acid ethyl ester. The formula is as follows:



The ratio free carboxyl group to ester group is preferably about 1:1. The mean molecular weight is e.g. about 250,000.

Such a copolymer will easily dissolve at pH values above 5.5 with the forming of salts.

Hydrophilic silicon dioxide is a known hydrophilic anti-tacking agent, the definition of which is known to the skilled man and can be found in the literature.

The functional coating may further comprise polyethyleneglycol, present in an amount from 5 to 30% by weight, based on the total weight of the functional coating. Stearic acid, dibutyl sebacate, propylene glycol and/or triethyl citrate can used in lieu of or in addition to polyethyleneglycol.

The functional coating usually represents from 0.5 to 6% by weight of the core weight.

The composition may further comprise an intermediate coating.

This coating which acts as a protecting layer comprises classical excipients, such as those recited above with respect to the core. For example, this intermediate coating comprises hydroxypropylmethylcellulose and polyethyleneglycol. This intermediate coating usually represents from 0.1 to 3% by weight of the core weight. In the case of a layer comprised of HPMC and PEG, the weight ratio HPMC:PEG is e.g. from 2 to 10.

The composition of the invention is a sustained release; preferably it provides an effective release of the active ingredient for a period of at least 8 hours, preferably at least 12 hours.

The invention is also concerned with a process for alleviating food effect in a pharmaceutical composition, comprising the step of coating a core comprising an active ingredient with the functional coating as defined above.

Thanks to the invention, it is now possible to avoid the food effect for virtually any drug. The invention makes it possible to operate with any drug, since the process does not involve any heating step, in contrast with the prior art.

Finally, the invention concerns a composition that is the precursor of the functional coating. Thus, the invention also provides an aqueous dispersion (suspension) of a gastroresistant polymer and of a hydrophilic silicon dioxide, present according to a weight ratio gastroresistant polymer:hydrophilic silicon between 0.75:1 and 8:1.

The dispersion (suspension) typically has a solid content from 3 to 50% by weight, e.g. about 10%.

The suspension may further comprise polyethyleneglycol dissolved in it, in an amount up to 15% by weight.

PREFERRED EMBODIMENTS

One preferred embodiment is a tablet comprising:

(a) a core comprising carbamazepine;

(b) a first layer comprising HPMC and polyethyleneglycol; and

(c) a second layer comprising a methacrylic copolymer, hydrophilic silicon dioxide and polyethyleneglycol.

EXAMPLES

The following examples illustrate the invention without limiting it.

Example 1. Carbamazepine.

The following core formulation was prepared

Ingredient	Amount per dosage unit (mg)
Carbamazepine	400.00
Aerosil 200®	3.00
Avicel PH 302®	100.00
Plasdone K90®	8.00
Denatured alcohol	290.00
Methocel K 100 LV®	125.00
Sodium stearylfumarate	17.00

Carbamazepine and Methocel® are mixed to Avicel and 50% of the amount of Aerosil 200® passed through a 0.5mm mesh size sieving screen. Plasdone® is dissolved in ethanol. The powder mixture is put into a mixer and wet with the solution. The resulting agglomerates are passed through a sieving screen of 0.062" (Co Mill®). Granules are dried to constant weight in an oven at 45°C (loss on drying with infrared balance = 1.5%). Dry granules are mixed to sodium stearyl fumarate and Aerosil 200® in drum mixer (Turbula® T2C). The resulting mixture is pressed into tablets of 657 mg and about 150 N hardness, using a Manesty Betapress® tableting machine fitted with 12 mm diameter punches.

These tablet cores were then coated with an intermediate coating of the following composition:

Ingredient	Amount per dosage unit (mg)
Pharmacoat 603®	5.50
Polyethyleneglycol 1450	1.00
Purified water	50.00

Pharmacoat 603® is HPMC, available from Shin-Etsu chemicals. Pharmacoat 603 and PEG 1450 are dissolved in water and the solution is sprayed onto the tablet cores in a Vector coating pan, using the following spraying parameters:

Inlet Air Temperature	55 - 60C
Outlet Air Temperature	40 - 45C
Spray Rate	5 - 8g/minute
Spray Pressure	30 psi
Pan Speed	16 rpm

These coated tablets were then coated a second time with a functional coating of the following composition:

Ingredient	Amount per dosage unit (mg)
Eudragit® L30D55	13.30 (Solid)
Syloid®244FP	4.00
Polyethyleneglycol 8000	2.70
Purified water	80.00

Eudragit® L30D55 is methacrylic copolymer available from Rohm. **IS THE VALUE 13.30 THE WEIGHT OF THE DISPERSION OR THE WEIGHT OF THE SOLIDS - Solids**

Syloïd® 244FP is hydrophilic silicon dioxide available from Grace Chemicals.

PEG 8000 is dissolved in 45% of amount of purified water. This solution is added to Eudragit suspension and stirred with paddle stirrer for 45 minutes. Syloïd® 244FP is suspended in the remaining part of water and the suspension is homogenized with a high-speed homogenizer Ultra Turrax® T25. The two suspensions are mixed and the mixture is sprayed onto the tablets in a Vector coating pan, using the following parameters:

Inlet Air Temperature	55 - 60C
Outlet Air Temperature	40 - 45C
Spray Rate	5 - 8g/minute
Spray Pressure	30 psi
Pan Speed	16 rpm

This coating is uncured, since no oven is used once the coating has been applied.

These tablets are tested for dissolution in standard apparatus type 1 of United States Pharmacopoeia. A 2% solution of sodium laurylsulfate in 0.01M potassium dihydrogenophosphate pH 6.8 buffer is used as dissolution medium. The amount of carbamazepine dissolved is recorded vs. time by using a Hewlett Packard HP8452A spectrophotometer. The curve is given in figure 1. It can

be seen that the composition provides an effective release of carbamazepine during about 12 hours.

For the clinical trials, this formulation was tested against the same Tegretol® XR, reference product from Novartis® in a two way cross study performed on 6 healthy volunteers. To get an evaluation of the efficiency of the coating, tablets of the above formulation were also tested against tablets of the same composition except that the functional coating was replaced by a classical (cosmetic) coating of the following composition:

Ingredient	Amount per dosage unit (mg)
Opadry®	15.00
Purified water	80.00

Opadry® comprises HPMC, HPC, titanium dioxide and PEG; it is available from Coloron.

Classical pharmacokinetics parameters Cmax and AUC were recorded, where:

- Cmax is the maximal plasma concentration reached during the study; and
- AUC is the area under the plasmatic concentration vs. time curve.

Results presented in table are ratios of parameters between test and reference products. Reference product is Tegretol®. Table 1 gives the results for the classical tablet while table 2 gives the results for the tablet of the invention.

Table 1

	$Cmax_{ref}/Cmax_{test}$	AUC_{ref}/AUC_{test}
Fasted conditions	1.01	0.99
Fed conditions	1.48	1.26

Table 2

	$Cmax_{ref}/Cmax_{test}$	AUC_{ref}/AUC_{test}
Fasted conditions	1.03	1.06
Fed conditions	1.07	1.03

From the above tables, it is clear that the classical tablet has a marked food effect while the tablet of the invention are free of any food effect.

Example 2. Verapamil.

In a manner similar as above, the following formulation was prepared.

Core:

Ingredient	Amount per dosage unit (mg)
Verapamil HCl	240.00
Avicel PH 101	25.00
Plasdone K30®	20.00
HPMC 15,000 cPs	35.00
HPMC 100 cPs	20.00
Silicon dioxide	1.50
Magnesium stearate	3.50

HPMC is hydroxypropylmethylcellulose.

Coating:

Ingredient	Amount per dosage unit (mg)
Eudragit® L30D55	7.50
Syloid®244FP	3.00
PEG 1450	1.50

Example 3. Oxibutynin.

In a manner similar as above, the following formulation was prepared.

Core:

Ingredient	Amount per dosage unit (mg)
Oxibutynin HCl	15.00
Avicel PH 101	24.50
Plasdone K30®	10.00
Polyox WSR	180.00
Silicon dioxide	3.00
Sodium stearyl fumarate	6.00
Vitamin E	2.00

Coating:

Ingredient	Amount per dosage unit (mg)
Eudragit® L30D55	5.55
Fumed silica	2.20
PEG 1450	1.10
Triethyl citrate	0.55

Fumed silica is hydrophilic silicon dioxide available from Grace Chemicals.

Triethyl citrate is a plasticizer.

The dissolution profile has been determined (medium is 750 ml phosphate buffer pH=6.8, basket 100 rpm). The results are the following:

Time (hr)	% dissolved
1	11
2	20
4	38
6	54
8	70
10	83
12	99

CLAIMS

1. A sustained release composition free of food effect comprising:

(a) a core comprising verapamil; and

(b) a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide.

2. The composition according to claim 1, in which the gastroresistant polymer is selected from the group consisting in uncured poly(meth)acrylic acids, cellulose and alkylcellulose-phtalates.

3. The composition according to claim 1, in which the functional coating further comprises polyethyleneglycol, present in an amount from 5 to 30% by weight, based on the total weight of the functional coating.

4. The composition according to claim 1, in which the functional coating represents from 0.5 to 6% by weight of the core weight.

5. The composition according to claim 1, in which the core comprises from 20 to 80% of active ingredient.

6. The composition according to claim 1, in which the core is comprised of granules compressed together.

7. The composition according to claim 1, which further comprises an intermediate coating.

8. The composition according to claim 7, in which the intermediate coating comprises hydroxypropylmethyl-cellulose and polyethyleneglycol.

9. A sustained release composition free of food effect comprising:

(a) a core comprising verapamil; and

(b) a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer comprised of uncured poly(meth)acrylic acids and from 10 to 40% of a hydrophilic silicon dioxide.

10. The composition according to claim 9, in which the functional coating further comprises polyethyleneglycol, present in an amount from 5 to 30% by weight, based on the total weight of the functional coating.

11. A sustained release composition free of food effect comprising:

(a) a core comprising verapamil; and

(b) a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer comprised of uncured poly(meth)acrylic acids, from 10 to 40% of a hydrophilic silicon dioxide and from 5 to 30% by weight of polyethyleneglycol.

12. The composition according to claim 1, providing effective release of the active ingredient for a period of at least 8 hours.

13. The composition according to claim 9, providing effective release of the active ingredient for a period of at least 8 hours.

14. The composition according to claim 11, providing effective release of the active ingredient for a period of at least 8 hours.

15. A process for alleviating food effect in a pharmaceutical composition, comprising the step of coating a core comprising verapamil with a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of an hydrophilic silicon dioxide.

16. The process of claim 15, in which the composition is as defined in claim 1.

17. The process of claim 15, in which the composition is as defined in claim 9.

18. The process of claim 15, in which the composition is as defined in claim 11.

ABSTRACT

The invention provides a sustained release composition free of food effect comprising:

(a) a core comprising verapamil; and

(b) a functional coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide.

The invention also provides a method for alleviating food effect in a verapamil pharmaceutical composition.

Attorney Docket No. 8674-000004

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

SUSTAINED RELEASE VERAPAMIL PHARMACEUTICAL COMPOSITION FREE OF FOOD EFFECT AND A METHOD FOR ALLEVIATING FOOD EFFECT IN DRUG RELEASE

the specification of which (check one)

[X] is attached hereto.

[ ] was filed on _____ as Application Serial No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application or to the patentability of the invention claimed therein in accordance with Title 37, Code of Federal Regulations, section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

			Priority Claim	
(Number)	(Country)	(Day/Month/Year filed)	Yes	No
(Number)	(Country)	(Day/Month/Year filed)	Yes	No
(Number)	(Country)	(Day/Month/Year filed)	Yes	No

DECLARATION AND POWER OF ATTORNEY

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States Provisional application(s) listed below:

PRIOR PROVISIONAL APPLICATIONS

_____ _____
(application serial number) (Month / Day / Year filed)

_____ _____
(application serial number) (Month / Day / Year filed)

I hereby claim the benefit under Title 35, United States Code, section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	**Filing Date**	**Status - patented, pending, abandoned**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint Monte L. Falcoff, Reg. No. 37,617, and each principal, attorney of counsel, associate and employee of Harness, Dickey & Pierce, P.L.C., who is a registered Patent Attorney, my attorney with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. I request the Patent and Trademark Office to direct all correspondence and telephone calls relative to this application to Harness, Dickey & Pierce, P.L.C., P. O. Box 828, Bloomfield Hills, Michigan 48303 (248) 641-1600.

Full name of sole or first inventor: Pawan Seth

Inventor's signature: _____

Date: _____

Residence: 10 Meryton, Irvine, California 92612

Citizenship: India

Post Office Address: same as above